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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/651,307	08/28/2003	Chia-Gee Wang	U 014776-3	9029
140	7590	05/08/2006	EXAMINER	
LADAS & PARRY 26 WEST 61ST STREET NEW YORK, NY 10023			WEDDINGTON, KEVIN E	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/651,307

Applicant(s)

WANG ET AL.

Examiner

Kevin E. Weddington

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-121 is/are pending in the application.
- 4a) Of the above claim(s) 1-114 and 118-121 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 115-117 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10-27-03; 4-12-04</u> . | 6) <input type="checkbox"/> Other: _____ |

Claims 1-121 are presented for examination.

Applicants' drawings filed August 28, 2003; the information disclosure statements filed October 27, 2003 and April 12, 2004 have been received and entered.

Applicants' election filed January 19, 2006 in response to the restriction requirement of December 15, 2005 has been received and entered. The applicants elected the invention described in claims 115-117 (Group III) with traverse.

Applicants' traverse of the restriction requirement is not deemed persuasive for reasons set forth in the Office action dated December 15, 2005.

The claims filed on August 29, 2003 are the best written set. The applicants should remain with these set of claims which set forth a clear interpretation of the invention by the Examiner.

Claims 1-114 and 118-121 are withdrawn from consideration as being drawn to the non-elected invention (37 CFR 1.142(b)).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent

either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 115 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 36 of copending Application No. 10/651,305. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application teaches a method of treating tumors or cancer in a human in need of such treatment with comprises the steps of:

(a) administering to the human a compound comprising a pre-selected element; and then

(b) irradiating a select region, in which tumorous or cancerous cells are located; and then line emission x-rays of an energy selected to cause emission of Auger electrons from said pre-selected element in a dose effective to cause disruption of intracellular components of said tumorous or cancerous cells; and

the copending application teaches a method of treating tumors or cancer in a human in need of such treatment, which comprises:

(a) administering to the human a compound which associates with DNA in cells of said human, said compound comprising a pre-selected element; and then

(b) irradiating a select region, in which cancerous cells having said compound associated with DNA are located; and then line emission x-rays of an energy selected

to cause emission of Auger electrons from said pre-selected element in a dose effective to disrupt DNA proximate to the pre-selected element.

Clearly, the compounds comprising a pre-selected element set forth in the present application can be associated with DNA in the cells of said human in the absence of evidence to the contrary since both applications are performing the same functions to treat tumors or cancer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 56 is not allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 115-117 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to a method of treating tumors or cancer in a human in need of such treatment with comprises the steps of:

(a) administering to the human a compound comprising a pre-selected element; and then

(b) irradiating a select region, in which tumorous or cancerous cells are located; and then line emission x-rays of an energy selected to cause emission of Auger electrons from said pre-selected element in a dose effective to cause disruption of intracellular components of said tumorous or cancerous cells.

The state of the prior art, The Cecil reference, teaches for the various known cancer types, there is no one specific chemotherapeutic agent that is effective for all types of cancer (See Table 198-5 at page 1065; Table 198-6 at page 1066; Table 198-8 at page 1068; and table 198-9 at page 1071).

The relative skill of those in the art is generally that of a Ph.D. or M.D.

The present invention is unpredictable unless experimentation is shown what types of tumors or cancers are treat with instant invention.

The breadth of the claims

The claims are very broad and inclusive to all types of tumors and cancers

The amount of direction or guidance provided and the presence or absence of working examples

Applicants' specification does not contain any working examples showing what types of tumors or cancers were treated and disrupted by the instant invention.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to how the instant invention will treat all types of tumors and cancers. Therefore, undue experimentation would be required to practice the invention as it is claimed in its current scope.

Claims 115-117 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be

patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 115-117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cash, Jr. et al. (6,366,801 B1) of PTO-1449 in view of Wang (5,627,871) of PTO-1449 and Ariel et al., Cancer, Vol. 20, Issue No. 5, pp. 793-804 (1967).

Cash, Jr. et al. teach the use of contrast agents that contains heavy elements from the upper half of the periodic table, such as iodine, gadolinium, or gold (See column 3, lines 1-9) are used in combination with x-rays to irradiate the tumor. Clearly, the Cash, Jr. et al., reference teaches the applicants' invention is old and well-known in the art.

The instant invention differs from the cited reference in that the cited reference does not teach the applicants' preferred x-rays (line emission x-rays). However, the secondary reference, Wang, teaches the preferred line emission x-rays to the well-known in the art. Therefore, one skilled the art would have assumed the

substitution of one type of x-ray for another type would produce and achieve the same results (to treat tumors) in the absence of evidence to the contrary.

The instant invention differs from the cited references in that the cited references do not teach the applicants' preferred compound that comprises a pre-selected element, rose bengal. However, the Ariel et al. reference is cited to show rose bengal as a well-known anticancer used to treat cancer of the liver. Clearly, for one skilled in the art to substitute or use other types of anticancer agents in place of the agents of the primary reference, would achieve the same results in the absence of evidence to the contrary.


Claims 115-117 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
April 27, 2006